

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

: H. SUSAKI et al.

Group Art Unit: 1614

Serial No.

: 09/674,526

(US National Stage of (PCT/JP99/02681)

Examiner: Russell

Filed

: November 21, 2000

For

: DRUG COMPLEX

RESUBMISSION OF INFORMATION DISCLOSURE STATEMENTS

Commissioner of Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Further to our facsimile of April 1, 2004, please find enclosed signed copies of the Information Disclosure Statement filed May 9, 2001 and the Supplemental Information Disclosure Statement filed June 5, 2001, including copies of the cited documents, accompanied by date stamped mailroom receipts evidencing filing of the same.

Should the Examiner have any questions, please contact the undersigned at the telephone number provided below.

Respectfully/submitted

Bruce H. Bernstein

Reg. No. 29,027

n/s

33,089

April 6, 2004 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191

. IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: H. SUSAKI et al.

Serial No.: 09/674,526

Group Art Unit: Not Known

Filed

: November 21, 2000

Examiner: Not Known

For

: DRUG COMPLEX

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97, and 1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited in International Application No. PCT/JP99/02681, including the description, International Search Report and International Preliminary Examination Report. Copies of the above-noted document were filed when entering the National Stage on November 21, 2000, and the Examiner is referred to these documents relating to the relevance of the cited information.

JP 6-87746, accompanied by an English language abstract;



JP 11-92405 A accompanied by an English language abstract

WO 92/14759, which is family member of JP 7-84481 B;

WO 94/19376, for the convenience of the Examiner attached is a U.S. family member U.S. Patent No. 5,688,931;

WO 97/46260

Abstracts of 10th Meeting of the Japan Society of Drug Delivery System, pp. 279 (1994);

Abstracts of 9th Annual Meeting of Japanese Society for the Study of Xenobiotics, pp. 292 (1994);

Abstracts of 19th Seminar of Trends in Research and Development, pp. D-9 - D-12 (1995);

Abstracts of 12th Colloid and Interface Technology Symposium, The Chemical Society of Japan, pp. 51-58 (1995);

Gene M. Dubowchik et al., "Monomethoxytrityl (MMT) as a Versatile Amino Protecting Group for Complex Prodrugs of Anticancer Compounds Sensitive to Strong Acids, Bases and Nucleophiles", Tetrahedron Letters, Vol. 38, No. 30, pp. 5257-5260 (1997); and

Gene M. Dubowchik et al., "Efficient Mitomycin C Coupling With Stable p-Nitrophenyl-Benzyl Carbonates Using N-Hydroxybenzotriazole as a Catalytic Additive", Tetrahedron Letters, Vol. 38, No. 30, pp. 5261-5264 (1997);

Applicants also bring the following documents to the attention of the Examiner: WO 98/13059;

Gene M. Dubowchik et al., "Cathepsin B-Sensitive Dipeptide Prodrugs.1. A Model Study of Structural Requirements for Efficient Release of Doxorubicin", Bioorganic & Medicinal Chemistry Letters, Vol. 8, pp. 3341-3346 (1998);

Gene M. Dubowchik et al., "Cathepsin B-Sensitive Dipeptide Prodrugs.2. Models of Anticancer Drugs Paclitaxel (Taxol®), Mitomycin C and Doxorubicin", Bioorganic & Medicinal Chemistry Letters, Vol. 8, pp. 3347-3352 (1998);

Franciscus M.H. de Groot et al., "Synthesis and Biological Evaluation of Novel Prodrugs of Anthracyclines for Selective Activation by the Tumor-Associated Protease Plasmin", J. Med. Chem., Vol. 42, pp. 5277-5283 (1999);

Ion Niculescu-Duvaz et al., "Self-Immolative Anthracycline Prodrugs for Suicide Gene Therapy", J. Med. Chem., Vol. 42, pp. 2485-2489 (1999);

Dan Niculescu-Duvaz et al., "Self-Immolative Nitrogen Mustard Prodrugs for Suicide Gene Therapy", J. Med. Chem., Vol. 41, pp. 5297-5309 (1998);

Richard B. Greenwald et al., "Drug Delivery Systems Employing 1,4- or 1,6-Elimination: Poly(ethylene glycol) Prodrugs of Amine-Containing Compounds", J. Med. Chem., Vol. 42, pp. 3657-3667 (1999);

Yu-Ling Leu et al., "Design and Synthesis of Water-Soluble Glucuronide Derivatives of Camptothecin for Cancer Prodrug Monotherapy and Antibody-Directed Enzyme Prodrug Therapy (ADEPT), J. Med. Chem., Vol. 42, pp. 2623-2628 (1999); and

Ruben G.G. Leenders et al., "Novel Anthracycline-spacer-β-glucuronide, -β-glucoside, and -β-galactoside Prodrugs for Application in Selective Chemotherapy", Bioorganic & Medicinal Chemistry, Vol. 7, pp. 1597-1610 (1999).

Copies of the above-noted documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicant respectfully requests that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

May 9, 2001

GREENBLUM & BERNSTEIN, P.L.C.

1941 Roland Clarke Place

Reston, VA 20191 (703) 716-1191

Applicants also bring to the Examiner's attention commonly assigned U.S. Application No. 09/147,342 (a copy of which is enclosed), which is a National Stage of PCT/JP97/01914, filed June 5, 1997, and which published as the above-noted WO 97/46420.

If any fees are necessary for consideration of this disclosure statement, the Commissioner is authorized to charge any required fee to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,

Car 33098

Bruce H. Bernstein

Reg. No. 29,027

COPY

GREENBLUM & BERNSTEIN, P.L.C. Intellectual Property Causes 1941 Roland Clarke Place Reston, VA 20191 (703) 716-1191

5/09/2001

File In: Mailroom The Patent Office Date stamp hereon is an acknowledgement that, on the date indicated, the Patent Office received the following:) Amendment () Claim of Priority & Certified) Executed Assignment and cover letter Copy of () by facsimile) Executed S.E.S. () S.E.S. Assertion () Declaration () Supplemental) Req. for Ext. of Time () New () Unexecuted) Fee Filing () Executed by facsimile Recording Issue) Transmittal Letter Extension MAY 0 9 2001 () Patent Application () Provisional () Reexam) Fee Transmittal) Reissue () Design) Maintenance Fee Payment) Continuation () CIP) PTOL-85B Issue Fee pages (w/abstract)) Letter to Draftsman _claims _ _ independent) Design Patent Application Transmittal _ sheets of drawings) Utility Patent Application Transmittal figures) Provisional Application Cover Sheet (X) I.D.S. form PTO-1449 &) Continued Prosecution Application References (X) as attached (CPA) Request Transmittal () as listed on) Request for Continued Examination (RCE) reverse including Submission) One self-addressed postcard) Cover Letter) Certification under 1.97(e)) Check No. for \$) Certificate of Mailing (C-O-M)) Rule 53b and 53f Letter for Returned Envelope Lapy of 1147,342 Unexecuted Application In the matter of : DRUG COMPLEX Applicant : Hiroshi SUSAKI Kazuhiro INOUE Hiroshi KUGA Application No. : 09/674,526 Filed : 2/13/2001 Patent No. Issued: Docket/: P20257 AT

Form PTO-1449

U.S. Department of Commerce Patent and Trademark Office Atty. Docket No. 2

Applicant

Serial No. 09/674,526

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

11	BY APPLICANT (Use several sheets if necessary)										H. SUSAKI et al.				
		(1	Use	seve	ral s	heet	s if	nece	essary)		Filing Date November 21, 2000	O	Group 1614		
										U.S. PATENT I	DOCUMENTS				•
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						от	HEI	R D	OCUMENT	S (Including Au	thor, Title, Date, Pe	rtinent Pages,	Etc.)		
		1	English Language Abstract of JP 6-87746.												
		2	English Language Abstract of JP 11-92405.												
		3	A	Abstracts of 10th Meeting of the Japan Society of Drug Delivery System, pp. 279 (1994). Abstracts of 9th Annual Meeting of Japanese Society for the Study of Xenobiotics, pp. 292 (1994). Abstracts of 19th Seminar of Trends in Research and Development, pp. D-9 - D-12 (1995). Abstracts of 12th Colloid and Interface Technology Symposium, The Chemical Society of Japan, pp. 51-58 (1995).								·			
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		7	Gene M. Dubowchik et al., "Monomethoxytrityl (MMT) as a Versatile Amino Protecting Group for Complex								olex				
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*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXAMINER

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Form PTO-1449)		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. P20257	Serial No. 09/674,526					
IN	FOF	RM.	ATION DISCLOSURE STATEMENT BY APPLICANT	Applicant H. SUSAKI et al.						
		(Ľ	Jse several sheets if necessary)	Filing Date November 21, 2000	Group 1614					
			OTHER DOCUMENTS (Including Au	thor, Title, Date, Pertinent Pages,	Etc.)					
		9	Gene M. Dubowchik et al., "Cathepsin B-Sensi	tive Dipeptide Prodrugs.1. A Mo	odel Study of Structural					
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~			(1998).							
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			Prodrugs of Amine-Containing Compounds", J. Med. Chem., Vol. 42, pp. 3657-3667 (1999).							
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